

PATENT
Attornev Docket No. 211352

Client Reference No. 20462-CPA-RI-RCF

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Number

RE38,687 E

Issued:

January 11, 2005

Name of Patentee:

Sogabe et al.

Title of Invention:

CREATINE AMIDINOHYDROLASE,

PRODUCTION THEREOF AND USE THEREOF

REQUEST FOR CERTIFICATE OF CORRECTION OF PATENT FOR APPLICANTS' MISTAKE (37 CFR 1.323)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 Certificate
DEC 0 8 2005

of Correction

Attn:

Decision and Certificate of Correction

Branch of the Patent Issue Division

Dear Sir:

It is requested that a Certificate of Correction be issued to correct errors found in the above-identified patent. Please note that these errors are of a typographical nature or character.

In particular, please note that the error in SEQ ID NO: 2 of the Sequence Listing was corrected and accepted in divisional U.S. Patent Application No. 10/807,228. For convenience, attached are copies of the "Declaration Under 37 C.F.R. § 1.132 of Atsushi Sogabe" and "Supplemental Declaration for Reissue Patent Application to Correct 'Errors' Statement (37 C.F.R. § 1.175)" submitted in the divisional application regarding the aforementioned typographical error. The errors at column 8, line 17, and in claim 55 (column 24, line 31) are minor typographical errors. The errors occurred in good faith. Correction thereof does not involve such changes in the patent as would constitute new matter or would require reexamination. All other errors listed on the attached Certificate of Correction did not originate with the Applicants, as will be apparent upon a comparison of the issued patent with the application as allowed. Accordingly, attached hereto is a Certificate of Correction, in duplicate, which indicates the requested correction.

The Commissioner is hereby authorized to charge the \$100.00 fee as required by 37 CFR 1.20(a) to Deposit Account No. 12-1216. A duplicate of this communication is enclosed for that purpose.

12/06/2005 RFEKADU1 00000024 121216 RE38687

01 FC+1811 100-00 DA

DEC 0 9 2005

Patent No. RE38,687

Issued: January 11, 2005

Patentee: Sogabe et al.

Respectfully submitted,

John Kilyk, Jr., Reg No. 20,763 LIX DIG, VOIT & MAJER, LTD.

LEMDIG, VOIT & MANER, LTL Two Prudential Plaza, Suite 4900 180 North Stetson Avenue

Chicago, Illinois 60601-6780 (312) 616-5600 (telephone)

Date: November 30, 2005 (312) 616-5700 (facsimile)

MAILING/TRANSMISSION CERTIFICATE UNDER 37 CFR 1.8 OR 1.10

1 hereby certify that this document and all accompanying documents are, on the date indicated below, being [6] deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed in the same manner indicated on this document.

Name (Print/Type)

John Kilyk, Jr.

Signature

Date

November 30, 2005



PATENT
Attorney Docket No. 226749
Client Reference: 20462-CPA-RI-RCE-DIV

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE.

In re Application of:

Sogabe et al.

Art Unit: 1652

Application No. 10/807,228

Examiner: E. Slobodyansky

Filed: March 23, 2004

For: CREATINE AMIDINOHYDROLASE, PRODUCTION THEREOF AND USE THEREOF

DECLARATION UNDER 37 C.F.R. § 1.132 OF ATSUSHI SOGABE

I, Atsushi Sogabe, do hereby declare:

- 1 I am a co-inventor of the subject matter disclosed and claimed in the above-identified patent application.
- The above-identified patent application identifies SEQ ID NO: 2 as the nucleotide sequence of a wild-type creatine amidinohydrolase gene. The amino acid sequence encoded by the gene is set forth in SEQ ID NO: 1.
- The above-identified patent application contains a typographical error in the nucleotide sequence of SEQ ID NO: 2. Specifically, nucleotide residue 435 of SEQ ID NO: 2 should by guanine (G), and not cysteine (C). Therefore, the codon at nucleotide residues 433-435 should be GAQ, and not GAQ. The deduced amino acid sequence of SEQ ID NO: 1 (which also appears in SEQ ID NO: 2) correctly sets forth the amino acid corresponding to the codon at nucleotide residues 433-435 as glutamine (Glu).
- 4 The correct nucleotide sequence that encodes SEQ ID NO: 1 could be readily sequenced by one of ordinary skill in the art as of 1996 from the source material of the amidinohydrolase gene derived from Alcaligenes faecalis TE3581, which has deposit accession number FERM P-14237. The above-identified application sets forth the source material at, for example, column 4. lines 7-10.

5 I hereby declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 05. 8. 18

Strushi Sogabe
Atsushi Sogabe



PATENT
Attorney Docket No. 226749
Client Reference No. 20462-CPA-RI-Div

SUPPLEMENTAL DECLARATION FOR REISSUE PATENT APPLICATION TO CORRECT "ERRORS" STATEMENT (37 C.F.R. 1.175)

Patent Application No. 10/807,228

Applicant: Sogabe et al.

Filed: March 23, 2004

TC/AU: 1652

Examiner: E. Slobodyansky

Docket No.: 226749-Tak (Client Reference No. 20462-CPA-RI-RCE-DIV)

Customer No.: 23460

As a below named inventors. I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name. I believe I am an original, first, and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

CREATINE AMIDINOHYDROLASE, PRODUCTION THEREOF AND USE THEREOF

I previously executed a Combined Declaration and Power of Attorney, submitted March 23, 2004, with respect to the subject application. I hereby reaffirm the statements made in the previously executed Combined Declaration and Power of Attorney.

In the previously executed Combined Declaration and Power of Attorney, I stated that I believed the original patent, U.S. Patent No. 6,080,553, to be partially inoperative by reason of claiming less than the applicants had a right to claim. I continue to have such a belief for the reasons stated in the previously executed Combined Declaration and Power of Attorney and this Supplemental Declaration for Reissue Patent Application.

The original patent describes and claims a creatine amidinohydrolase, reagent, method of production thereof, and method of use thereof. The creatine amidinohydrolase is defined by physicochemical properties, such as action, optimum temperature, optimum pH, Km value, molecular weight, and isoelectric point. The isoelectric point (p1) for the creatine amidinohydrolase is recited in the specification and claims of the original patent as 3.5, but in fact was and is 4.5. Additionally, we have identified a typographical error in the nucleotide sequence of SEQ ID NO: 2. Specifically, nucleotide residue 435 of SEQ ID NO: 2 is recited as cysteine (C), but in fact was and is guanine (G). These errors and any other errors (i.e., all errors) were made without any deceptive intent on the part of the applicants and were discovered only relatively recently. To rectify these and other errors (such as the failure to claim a method of preparing a creatine amidinohydrolase as recited in the new claims added by way of the present reissue application, the specification and claims of the original patent have been amended by way of specification, localizin, and abstract changes previously filed in the present reissue application as well as in U.S. Patent Application No. 09940,941 (U.S. Patent No. RE38687), each of which is a divisional reissue of the original patent. Every error in the original patent which was corrected in the present reissue application, in son covered by a prior outh/declaration submitted in this reissue application, arose without any deceptive intention on the part of the applicants.

I declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

The man of sole of his instance. Also shi sough
Inventor's signature Alush Jogale
Inventor's signature Hawky Logade Date Sep 30, 2005 Country of Citizenship: Japan
Residence: Tsuruga-shi, Fukui, Japan (city/state or country)
Post Office Address: c/o Toyo Boseki Kabushiki Kaisha, Tsuruga Institute of Biotechnology, 10-24, Toyo-cho, Tsuruga-shi, Fukui 914 Japan (complete mailing address)
Full name of second joint inventor, if any: TAKASHI HATTORI
Inventor's signature TAKASHI HATTORI
Date Sep. 27. 2005 Country of Citizenship: Japan
Residence: Tsuruga-shi, Fukui, Japan (city/state or country)
Post Office Address: c/o Toyo Boseki Kabushiki Kaisha, Tsuruga Institute of Biotechnology, 10-24, Toyo-cho, Tsuruga-shi, Fukui 914 Japan (complete mailing address)
Full name of third joint inventor, if any: YOSHIAKI NISHIYA
Inventor's signature <u>Yeskaki Nishiya</u>
Date Sup. 27, 2005 Country of Citizenship: Japan
Residence: Tsuruga-shi, Fukui, Japan (city/state or country)
Post Office Address: c/o Toyo Boseki Kabushiki Kaisha, Tsuruga Institute of Biotechnology, (complete mailing address) (complete mailing address)
Full name of fourth joint inventor, if any: YOSHIHISA KAWAMURA
Inventor's signature . 405 hichisa Kawamura
Date <u>320, 22. 2005</u> Country of Citizenship: Japan
Residence: Tsuruga-shi, Fukui, Japan (city/state or country)
Post Office Address: c/o Toyo Boseki Kabushiki Kaisha, Tsuruga Institute of Biotechnology, 10-24, Toyo-cho, Tsuruga-shi, Fukui 914 Japan (complete mailing address)



PATENT Attorney Docket No. 226749 Client Reference No. 20462-CPA-RI-Div

SUPPLEMENTAL DECLARATION FOR REISSUE PATENT APPLICATION TO CORRECT "ERRORS" STATEMENT (37 C.F.R. 1.175)

Patent Application No. 10/807,228

Applicant: Sogabe et al.

Filed: March 23, 2004

TC/AU: 1652

Examiner: E. Slobodyansky

Docket No.: 226749-Tak (Client Reference No. 20462-CPA-RI-RCE-DIV)

Customer No.: 23460

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I declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor: ATSUSHI SOGABE
Inventor's signature Atushi Logable Date Lep 40, 2005 Country of Citizenship: Japan
Date Jep. 30, 2005 Country of Citizenship: Japan
Residence: Tsuruga-shi, Fukui, Japan (city/state or country)
Post Office Address: c/o Toyo Boseki Kabushiki Kaisha, Tsuruga Institute of Biotechnology, 10-24, Toyo-cho, Tsuruga-shi, Fukui 914 Japan (complete mailing address)
Full name of second joint inventor, if any: TAKASHI HATTORI
Inventor's signature TAKASHI HATTORI
Date <u>Sep. 27 → 200 S</u> Country of Citizenship: Japan
Residence: Tsuruga-shi, Fukui, Japan (city/state or country)
Post Office Address: c/o Toyo Boseki Kabushiki Kaisha, Tsuruga Institute of Biotechnology, 10-24, Toyo-cho, Tsuruga-shi, Fukui 914 Japan (complete mailing address)
Full name of third joint inventor, if any: YOSHIAKI NISHIYA
Inventor's signature Yoshiaki Nishiya
Date Sy. 27, 2005 Country of Citizenship: Japan
Residence: Tsuruga-shi, Fukui, Japan (city/state or country)
Post Office Address: c/o Toyo Boseki Kabushiki Kaisha, Tsuruga Institute of Biotechnology, 10-24, Toyo-cho, Tsuruga-shi, Fukui 914 Japan (complete mailing address)
Full name of fourth joint inventor, if any: YOSHIHISA KAWAMURA
Inventor's signature yoshihisa Karamura
Date Sep. 22. 2005 Country of Citizenship: Japan
Residence: Tsuruga-shi, Fukui, Japan (city/state or country)
Post Office Address: c/o Toyo Boseki Kabushiki Kaisha, Tsuruga Institute of Biotechnology, 10-24, Toyo-cho, Tsuruga-shi, Fukui 914 Japan (complete mailing address)

PATENT
Attorney Docket No. 226749
Client Reference: 20462-CPA-RI-RCF-DIV

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Sogabe et al.

Art Unit: 1652

Application No. 10/807,228

Examiner: E. Slobodvansky

Filed: March 23, 2004

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PRODUCTION THEREOF AND USE THEREOF

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- 3 The above-identified patent application contains a typographical error in the nucleotide sequence of SEQ ID NO: 2. Specifically, nucleotide residue 435 of SEQ ID NO: 2 should by guanine (G), and not cysteine (C). Therefore, the codon at nucleotide residues 433-435 should be GAQ, and not GAQ. The deduced amino acid sequence of SEQ ID NO: 1 (which also appears in SEQ ID NO: 2) correctly sets forth the amino acid corresponding to the codon at nucleotide residues 433-435 as glutamine (Glu).
- 4 The correct nucleotide sequence that encodes SEQ ID NO: 1 could be readily sequenced by one of ordinary skill in the art as of 1996 from the source material of the amidinohydrolase gene derived from Alcaligenes faecalis TE3581, which has deposit accession number FERM P-14237. The above-identified application sets forth the source material at, for example, column 4, lines 7-10.

I hereby declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: '05. 8. 18

Atsushi Sogabe

PATENT NO. : RE38,687 E

DATED : January 11, 2005

INVENTOR(S): Sogabe et al.

It is certified that errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title Page

Item (57): ABSTRACT: "following reaction;" should read as --following reaction:--.
"Molecule weight" should read as --Molecular weight--.

Column 1,

Line 32, "chronic neophritis, acute neophritis" should read --chronic nephritis, acute nephritis--.

Column 2,

Line 3, "genus, Alcaligenes" should read --genus Alcaligenes--.

Column 2.

Line 15, "cell lines" should read --cell line--.

Column 2.

Line 34, "creatine and" should read --creatine--.

Column 4,

Line 43, "incubated" should read --inoculated--.

Column 4.

Line 54, "obtain" should read --obtained--.

Column 5.

Line 6, "microorganisms" should read --microorganism--.

Column 6,

Line 11, "on a rate method" should read --or a rate method--.

MAILING ADRESS OF SENDER:

John Kilyk, Jr., Reg. No. 30,763 Leydig, Voit & Mayer, Ltd. Two Prudential Plaza, Suite 4900 180 North Stetson Avenue Chicago, Illinois 60601-6780 **PATENT NO. RE38,687**

PATENT NO RE38.687 E

DATED : January 11, 2005 INVENTOR(S) : Sogabe et al.

It is certified that errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 6,

Line 27, "detecting the creatine" should read --detecting creatine--.

Column 6.

Line 37, "peroxide activity" should read --peroxidase activity--.

Column 6,

Line 40. "lactoperoxidase" should read --.lactoperoxidase--.

Column 6.

Line 45, "hydrozine" should read --hydrazine--.

Column 7.

Line 19 (table), "0.3 H" should read --0.3 M--.

Column 7,

Line 23 (table), "sarcosine cridase" should read --sarcosine oxidase--.

Column 7,

Line 42 (equation), "dilutions fold" should read --dilution fold--.

Column 8.

Line 17, "creatinine" should read --creatine--.

Column 8.

Line 20, "restriction enzymes" should read --restriction enzyme--.

MAILING ADRESS OF SENDER:

John Kilyk, Jr., Reg. No. 30,763 Leydig, Voit & Mayer, Ltd. Two Prudential Plaza, Suite 4900 180 North Stetson Avenue Chicago, Illinois 60601-6780 PATENT NO. RE38,687

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It is certified that errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 8.

Line 42, "obtained in" should read --cultured in--.

Column 9.

Line 26, "record" should read --reduced ---

Column 9,

Line 39, "the ration of two kinds" should read -- the ratio of the two kinds --.

Column 9,

Line 40, "concentration + activity" should read --concentration ÷ activity --.

Column 9,

Line 44, "20,00" should read --20,000--.

Column 9,

Line 58, "filtration were" should read --filtration, were--.

Column 10,

Line 55, "or creatine amidinohydrolase" should read -- of creatine amidinohydrolase --.

Column 12.

Line 34, "Km value" should read --Km values--.

Column 13,

Line 1, "wild certainty" should read --wild creatine--.

Sequence Listing,

SEQ ID NO: 2, codon 433-435: "GAC" should read as --GAG--.

MAILING ADRESS OF SENDER:

John Kilyk, Jr., Reg. No. 30,763 Leydig, Voit & Mayer, Ltd. Two Prudential Plaza, Suite 4900

180 North Stetson Avenue Chicago, Illinois 60601-6780 **PATENT NO. RE38,687**

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : RE38,687 E

DATED : January 11, 2005

INVENTOR(S): Sogabe et al.

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Column 21,

Line 47, "having a following" should read --having the following--.

Column 22.

Line 25, "measuring-absorbance" should read --measuring absorbance--.

Column 22,

Line 38, "measuring-absorbance" should read --measuring absorbance--.

Column 22,

Line 45, "measuring-absorbance" should read --measuring absorbance--.

Column 23.

Line 1, "at temperature" should read --at a temperature--.

Column 24,

Line 26, "in sample" should read --in a sample--.

Column 24,

Line 28. "claim 15" should read --claim 38--.

Column 24,

Line 31, "and enzyme" should read --an enzyme--.

Column 24.

Line 41, "hydrozine" should read --hydrazine--.

MAILING ADRESS OF SENDER:

John Kilyk, Jr., Reg. No. 30,763 Leydig, Voit & Mayer, Ltd. Two Prudential Plaza, Suite 4900 180 North Stetson Avenue Chicago, Illinois 60601-6780

PATENT NO. RE38,687

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

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PATENT NO. RE38,687

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DATED January 11, 2005

Sogabe et al. INVENTOR(S):

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Sequence Listing. MAILING ADRESS OF SENDER:

SEQ ID NO: 2, codon 433-435: "GAC" should read as --GAG--

PATENT NO. RE38.687

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